Graduate Certificate in Health Products Regulation

GMS5108: Clinical Studies and Evaluation of Health Products

17 – 21 January 2022

Day 1 – 17 Jan, Mon

	Topic	Speaker/ Organisation
9.00am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
Session 1: Introduction to Clinical Trials		
9.15am	**Workshop Briefing**	**Dr Uttara Soumyanarayanan** Education Associate II CoRE, Duke-NUS Medical School
9.25am	**Opening of Graduate Certificate Programme**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.45am	**Trends in Clinical Trial Landscape** • Limitations of conventional RCTs • Adaptive trials • Pragmatic trials	**Dr Uttara Soumyanarayanan** CoRE
10.15am	**Break**	
10.45am	**Overview of Clinical Trials (Local)** • Legal Framework • Clinical Trial Registers • PI-initiated vs pharma-initiated development trials • Roles & responsibilities of different stakeholders	
11.45am	**Ethical and Legal Aspects** • IRB, Informed Consent • Impact of HBRA guidance reforms on informed consent forms • Use of Placebo • Patient Safety	
12:30pm	**Lunch**	
2.00pm	**Group Activity:** Review Patient Information Sheet and Informed Consent Form to find deficiencies	
2.45 pm	**Clinical Trial Operations** • 5 project phases of clinical trials • Key functions and process in CTOs • The site Perspective & the Patient Perspective • Clinical Trials 2.0	
3.45pm	**Break**	
4.15pm	**Innovations in Clinical Trials** • Novel therapeutics and Trial Designs	
5.15pm	**End**	

Day 2 – 18 Jan, Tue

	Topic	Speaker/ Organisation
8.30am	Individual and group assessment I	
Sesssion 2: Nonclinical and Clinical Development of Pharmaceutical Products		
9.30am	**Nonclinical Development of Pharmaceuticals**	
10.30am	**Break**	
11.00am	**Clinical Development of Pharmaceutical Products** • Objectives and design of Phase 1-3 trials • Endpoints and Outcomes	
12.30pm	**Lunch**	
1.30pm	**Oncology vs Non-Oncology Drug Development** • Clinical endpoints, surrogate markers, biomarkers • Single arm studies • Stratification variables • Case examples of recent approvals that have interesting learning points • Drug development expedited approval pathways	
2.30pm	**GCP Inspections in Singapore** • Quality of clinical trials • GCP Inspection Framework in Singapore • How to prepare for GCP Inspections	
3.30pm	**Practicum I** • Nonclinical data/development • Phase 1 Clinical Trials	
4.00pm	**Break**	
4.30pm	**Practicum I continued**	
5.30pm	**End**	

Day 3 – 19 Jan, Wed

	Topic	Speaker/ Organisation
8.30am	Individual and group assessment II	
Session 3: Clinical Trial Data Analysis & Regulatory Decision-Making		
9.30am	**Utility of PK/PD Across Different Clinical Trial Phases** • Dosing regimen • Time to steady state • Bioequivalence studies (Bridging Formulations, Generics) • Clinical Pharmacology (Food effect, DDI) • Clinical Trial Simulation	
10:15am	**Practicum II: Phase 2 trials** • Analysis of safety and efficacy data of Phase 2a • Design criteria for Phase 2b trials	
10:45am	**Break**	
11:00am	**Practicum II continued**	
12:15am	**Lunch**	
1:30pm	**Statistical Principles for Clinical Trial Data Analysis** • Concepts for analysing trial data: p-value, CI, sample size, power • Coherence and validation of primary endpoints • Interim Analysis • Judgement – Clinical Relevance and alignment to practice guidelines • Case examples	
3.00pm	**Break**	
3.30pm	**Considerations in regulatory decision-making of CTA** • Documents to consider • ICH E8 guideline • Review of clinical trial protocol	
4:30pm	**Experience sharing by AVAREF**	
5.00pm	**End**	

Day 4 – 20 Jan, Thur

	Topic	Speaker/ Organisation
8.30am	**Individual and group assessment III**	**CoRE Education Team**
9.30am	**Considerations in regulatory decision-making of MAA (Early Phase)**	
10.30am	**Break**	
11.00am	**Considerations in regulatory decision-making of MAA (Late Phase)**	
12.00pm	**Lunch**	
1.00pm	**Safety data analysis and reporting in Clinical Trials** • Influence of nonclinical data on safety assessment plan • Safety analysis plan • Common AE templates/tools • Severity, AEs, safety parameters measured • Analysis: Safety monitoring and reporting	
2.00pm	**Practicum III: Phase 3 design and data analysis** • Phase 3 trials: design, choosing endpoints, powering the trial • Phase 3 trials: Review of safety data • Regulatory decision-making	
3.00pm	**Break**	
4:45pm	**Networking Activity**	**CoRE Education Team**
5.15pm	**End**	

Day 5 – 21 Jan, Fri

	Topic	Speaker/ Organisation
8.30am	**End of the Module assessment (EOM)**	**CoRE Education Team**
9:30am	**Review of EOM Assessment**	
10:15	**Pre-panel Preparation**	
10.45am	**Break**	
Session 4: Innovations in Clinical Trials		
11.15am	**Fundamentals of MRCT** • ICH E17 Guideline for MRCT • Global drug development: Industry perspective • CTD and region-specific Information • Resolving conflicts between MRCT and domestic drug development • Case Example: Regulatory Decision-Making	
12.30pm	**Lunch**	
1.30pm	**Pharmacogenetics and Ethnicity** • Case Examples	
2.15pm	**Global Clinical Trials: Operational Perspectives** • Assessing site feasibility • Site Qualification	
3.15pm	**Break**	
3:30pm	**Panel Session** • New trial design, new clinical endpoints • Patient centric approach: PROs, patient engagement and education • Role of big data in post approval phase and RWE	
4.45pm	**Workshop conclusion**	**Prof Silke Vogel** CoRE
5.00pm	**End**	